DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 10,2014

Denali Corporation
Jan G. Stannard
President
134 Old Washington Street
Hanover, MA 02339

Re: K141503
Trade/Device Name: Denali 501 Cement
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: August 7, 2014
Received: August 19, 2014

Dear Dr. Stannard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) Number
(if known)

K141503

Device Name

Denali 501 Cement

Indications for Use:

Denali 501 Cement is a two part, resin-based cement recommended for the bonding of ceramic, metal and composite restorations. **For Use only by a Licensed Dentist. Rx Use Only.**

Please do not write below this line. Continue on another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☒ Prescription Use (Per 21 CFR 801.109) or ☐ Over-The-Counter Use

denali corporation
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510 (k) Summary

June 22, 2014

ADDRESS	DENALI CORPORATION 134 Old Washington Street / Hanover, MA 02339-1629
OWNER/CONTACT PERSON	Dr. Jan G. Stannard TEL: 781-826-9190 / FAX: 781-826-4465 j.stannard@denalicorporation.com
TRADE NAME	Denali 501 Cement
COMMON NAME	Resin Cement
CLASSIFICATION NAME	DENTAL CEMENT (21 CFR 872.3275, Product Code EMA)
REGISTRATION	3006367836
PREDICATE DEVICES	Cercom II Cement/Denali Corporation (K132393), Variolink Cement/Ivoclar (K971372), Tempbond with Triclosan Cement/Kerr (K053565).
EQUIVALENCE	The predicate products have been found substantially equivalent under the 510(k) premarket notification process as Class II Dental Devices under CFR EMA 872.3275, Dental Cement.
DEVICE DESCRIPTION	Denali 501 Cement is a two part, resin-based cement recommended for the bonding of ceramic, metal and composite restorations. Denali 501 contains polymerizable monomers that can set in either a light activated mode or set upon mixing Part A and Part B. When set the resin has a low solubility in water to act as a long term cement.
INTENDED USE	Denali 501 Cement is a resin-based cement recommended for the bonding of ceramic, metal and composite restorations. **For Use only by a Licensed Dentist. Rx Use Only.**
TECHNOLOGICAL CHARACTERISTICS SUMMARY	Denali 501 Cement has the same technological characteristics as the predicate devices Temp Bond and Variolink including: design, composition, biocompatibility, performance, ageing, intended use, safety and effectiveness, physical characteristics, setting, solubility, film thickness, depth of cure and mechanical properties (tensile and compressive strength).
BIOCOMPATIBILITY	Denali 501 Cement was found to be biocompatible, and is consistent in formulation to Tempbond and Variolink, in its intended use, biocompatibility, and properties compared to Tempbond and Variolink.
SUBSTANTIAL EQUIVALENCE DETERMINATION AND SUMMARY	Denali 501 Cement is substantially equivalent in design, composition, biocompatibility, performance, ageing, intended use, and safety and effectiveness to Tempbond and Variolink. This assessment is based upon a comparison of the physical and mechanical characteristics (tensile strength, com pressive strength), solubility, film thickness, depth of cure, and setting time. The results of these tests are consistent with values of Tempbond and Variolink.
CONCLUSIONS	Denali 501 Cement has been found to be substantially equivalent in design, composition, ageing, biocompatibility, performance, intended use, and safety and effectiveness to Tempbond and Variolink.